PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant:	Chapoulaud et al.
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Commissioner for Patents
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DECLARATION OF CRAIG A. ANDREIKO UNDER RULE 131 (37 CFR 1.131)

In support of the response of December 2, 2003, to the office action dated June 2, 2003, the Declarant, Craig A. Andreiko states:

1. Eric Chapoulaud, Mark Payne and I are inventors of the subject matter of the present application. Mark Payne and I are also inventors of the subject matter of U.S. Patent No.5,431,562 and other related patents and applications, the features of which are included in the custom orthodontic method and system to which the present application is directed.

2. I have read the declaration of Joseph R. Jordan dated December 1, 2003. I was present at the demonstration, referred to in his declaration, of the software to him by Eric Chapoulaud, which demonstration occurred prior to November 30, 1999, and I participated in the making of the slides referred to in his declaration and the sending of the slides to him prior to November 30, 1999.

3. The demonstration referred to in paragraph 2 above was one of a series of successful operations of the system prior to that time that began with the system described in the prior patents referred to in paragraph 1 above and continued with ongoing replacement of the components of that system with, and the addition of features and improvements by, the features described in the present application. Each of those operations of the system were conducted on data from three-dimensional information from the mouth of a patient of the shapes of the teeth of the patient communicated to us at our laboratory at Ormco Corporation in Glendora, California from an orthodontist who was treating the patient, usually in a remote state. Typically, the communication of the information

included the shipment to us of either an impression of the patient's teeth in malocclused positions or a plaster model thereof.

4. For the demonstration referred to in paragraph 2 and other system operations referred to in paragraph 3, three-dimensional data was entered into a computer at our lab of which Eric Chapoulaud was the principal operator. The data was generated by scanning a plaster model, as referred to paragraph 3, on a laser scanner as illustrated in Fig. 3 of the present application and described in the specification: The computer processed the data and displayed the views depicted in Figs. 3A, 3B, 4, 4A, 4B and 4C of the present application. On these views, Eric and the computer program interactively selected landmarks and other parameters for use in the calculation of suggested tooth positions to correct the malocclusion of the patient's teeth.

5. For the demonstration referred to in paragraph 2, the person viewing the display, in this case Eric, clicked on a command button to initiate the "set-up", in response to which the computer calculated suggested finish positions for the teeth, whereupon the teeth were redisplayed in the calculated finish positions. With this redisplay, the computer window on the display presented to the person viewing the display a set of controls as illustrated, for example, in Figs. 5A and 5C of the present application that allowed the person viewing the display to translate any selected tooth in any of three dimensions (occlusal/gingivally, mesial/distally and labial/lingually) and to rotate any selected tooth through any of three angles (torque, tip or rotation). The software operated to accept any changes or adjustments to the calculated tooth positions or orientations and to recalculate finish positions based on the adjustments entered through the controls on the display by the person viewing the display. The redisplayed positions of the teeth are as those illustrated in Figs. 5A-5D.

6. In operating the software for the features discussed in paragraph 5 above, Eric manipulated the screen controls to test the function and limits of the software.

7. I am an orthodontist licensed in the state of California. I routinely consulted with treating orthodontists who were treating orthodontic patients and who sent us three-dimensional information of the shapes of the teeth of their patients in the course of performing clinical tests of our custom appliance system. Prior to the demonstration referred to in paragraph 2 above, I, either alone or with Eric, viewing the display and operating the on-screen controls and other system operations referred to in paragraph 5 above, to change the calculated positions of the teeth to better achieve some orthodontic treatment goal. I then evaluated on the screen the recalculated positions of the teeth that

embodied the changes I had entered and entered a command into the computer that accepted the positions as so recalculated.

8. During the demonstration, Eric, after operating the system as discussed in paragraph 5 above, or I, after operating the system as described in paragraph 7, entered a command that caused the computer to design a custom orthodontic appliance, and then display the designed appliance on the display as illustrated in Figs. 5E, 5F and 5G. The appliance was displayed along with controls that allowed the person viewing the display to change parameters of the designed appliance, then to recalculate the appliance design that embodied the entered changes.

9. The system having the features discussed above were all functioning and operated successfully prior to November 30, 1999.

10. Prior to the demonstration referred to in paragraph 2 above, custom orthodontic appliances were manufactured based on designs that resulted from my operation of the system as set forth in paragraphs 7 and 8 based on three-dimensional data of real patients, including the brackets, archwires and jigs illustrated in Figs. 7A and 7C, as well as the brackets and archwires according to the methods set forth in the patents referred to in paragraph 1.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Craig A. Andreiko

12-1-03
Date